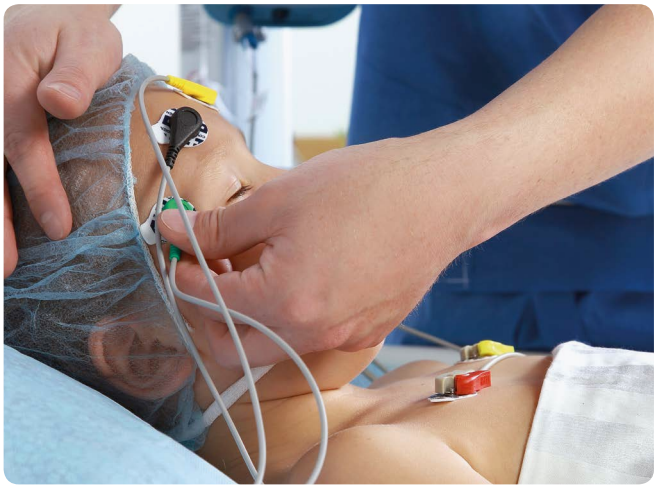
OEM Solutions for Anesthesiology and Respiratory Support

In biomedical signal processing, gas monitoring and respiratory support since 1989



Content

By developing and manufacturing advanced medical solutions we help doctors save lives

About

Triton Electronic Systems develops and supplies customized solutions for medical device industry since 1989. We focused on gas monitoring solutions and biomedical signal processing.

Our strategy is to provide ready-to-use and plug&play solutions for our customers, to support your developments and to reduce your leadtime for launching new functions to the market.

Our main values

- Fast and easy integration
- Highest protection (IP, EMC, safety)
- Regulatory & documentary support
- Original design and private labelling
- Cutting edge patented techologies

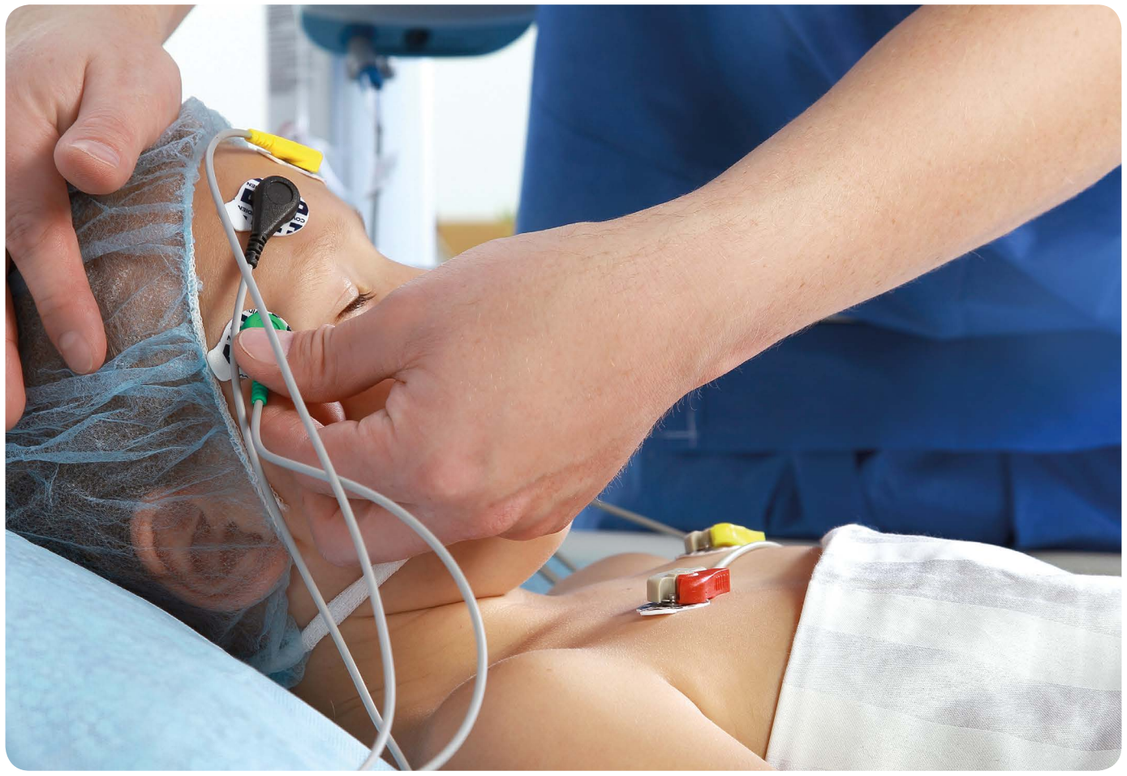
Inspired & expired gas monitoring (CO_2, O_2) | Respiratory monitoring | Volatile anesthetics monitoring | Vital signs monitoring | Cardiac output monitoring | Sedation monitoring

Gross floor area	6,900 sq.m
Employees	180
Design engineers	56
Selling to countries	>40

Depth of Anesthesia and Sedation Module

Complete solution for anesthesiologists:
Monitoring of Sedation Level

CE
0483

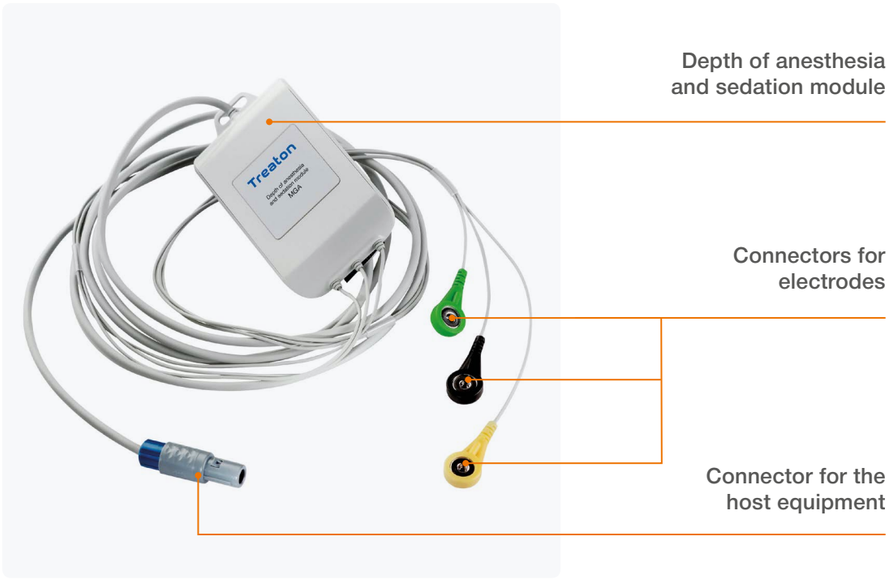


Depth of anesthesia and sedation module is designed to provide long and continuous monitoring of the Brain Activity Index (AI).

Application: anesthesiology, including perioperative period, resuscitation, intensive care, procedural sedation.

This is the solution for the daily routine depth of anesthesia monitoring, a standard monitoring tool in a medical institution, thereby increasing the patient's safety and quality of patient care.

Depth of anesthesia and sedation module can be connected to the monitoring host device and transfers parameters of the brain activity index, signal quantity index, electromiographic component suppression rate and additional states and statuses.



Identified Parameters

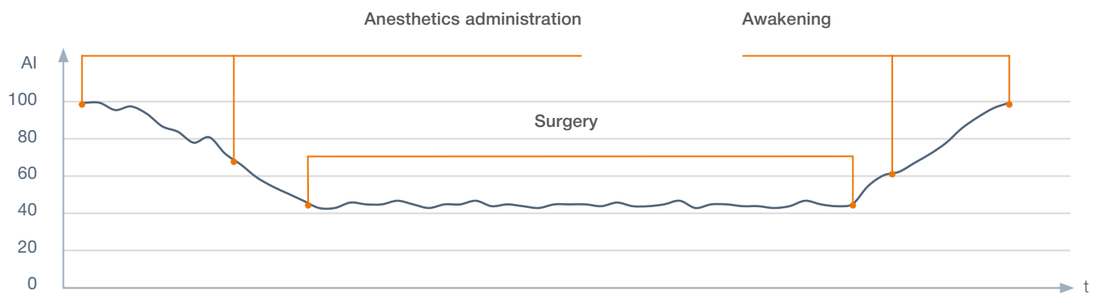
AI	Brain Activity Index	Indicates the level of consciousness depression by analyzing EEG, taking into account information on typical signs of anesthetics' impact on patients
SR	EEG Signal Suppression Rate	Reflects the relative duration of EEG suppression segments in the current time interval
SQI	EEG Signal Quality Index	Reflects the accuracy level of calculated AI (Brain Activity Index)
EMG	Electromyographic component level	Indicates the level of electrical activity of facial muscles
Z1, Z2, Z3	Electrode impedance	Demonstrates the quality of electrodes application and electrodes' electric contact with the patient's skin

MGA Module

Interpreting AI (Brain Activity Index) Data*

AI value	Clinical stages of anesthesia	Clinical signs
90–100	Awake	
80–90	Anesthesia stage I – light sedation	Incomplete awakening, patient opens eyes and maintains visual contact in response to a voice for 10 seconds or less
60–80	Anesthesia stage II – sedation	Patient moves and opens eyes in reaction to voice but does not fix the eyes – no visual contact or no response to voice but eye movements and eye opening after a physical stimulation persists
0–60	Anesthesia stage III – surgical state	No response to voice or physical irritants
30–40	Anesthesia stage IV – deep anesthesia, BS (burst – suppression) patterns emerge	
20–30	Anesthesia stage V – deeper anesthesia compared to stage IV, length of suppression episodes may reach 10 seconds	
0–10	Anesthesia stage VII – extremely deep anesthesia, suppression episodes constitute 75% and more of the whole signal duration	

* According to a generally accepted classification of anesthesia stages.



Advantages of Anesthesia Depth Monitoring

MGA Module

Potential Effects of Inadequate Sedation*

With continuously raising requirements to ensuring patient's safety, physicians have to provide more careful control of using anesthetics, hypnotic drugs or sedatives. According to the statistics, more than 69% of patients demonstrate inadequate sedation – either insufficient or too deep. This can cause adverse effects both during the surgery and at the post-operative stage.

Potential Effects of Inadequate Sedation*

Insufficient sedation	Excessive sedation
Excitation	Depressed breathing, hypotonia, depressed gastrointestinal tract motility
Sleep violations	Prolonged depression of consciousness
Myocardial ischemia	Prolonged ventilation duration
Unsynchronized ventilation	Prolonged stay at ICU and clinic in general
Self-extubation	Increased healthcare costs
Posttraumatic distress and depression	

* Mehta S. Sedation Strategies in the Critically Ill // Yearbook of Intensive Care and Emergency Medicine, 2005.

Using MGA minimizes the adverse effects of inadequate sedation, ensuring optimal and predictable sedation level and patient's quicker recovery from anesthesia.

Preventing Anesthesia Awareness

Anesthesia awareness is post-operative recollections of the event happening during general anesthesia, caused by misalignment between the need for anesthetic and its delivery.

The following patients are in the risk group for anesthesia awareness:

- taking opiates or alcohol;
- using neuromuscular relaxants;
- suffering from respiratory problems;
- with previous cases of accidental awakening during the surgery;
- with a co-pathology;
- elderly.

Anesthesia awareness cannot be measured directly. Traditional clinical signs like motions, tachycardia, hypertension, pupillary reaction and lacrimation are supposed to be unreliable predictors of anesthesia awareness but they must be monitored in every patient and considered substantially.

Individual Selection of Sedative Doses

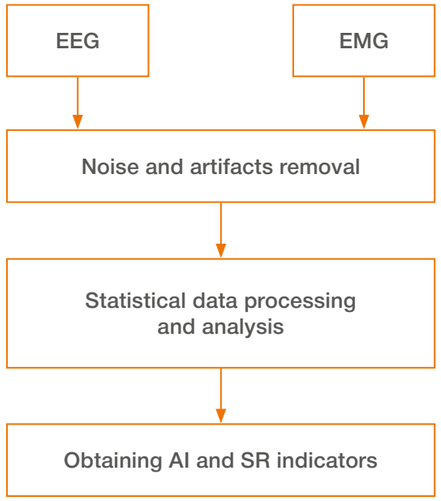
Selecting the optimal drug dosage with MGA is based on EEG analysis and displaying the AI (Brain Activity Index), taking into account individual body features and the clinical situation.

This approach ensures:

- maximum safety and efficiency of the delivered anesthetic support;
- reducing the risk of drugs' adverse effect on the body;
- saving expensive drugs.

Algorithm of AI (Brain Activity Index) Calculation

Anesthesia depth assessment is based on a comprehensive electroencephalogram (EEG) analysis using unique algorithms developed by Triton Electronic Systems engineers. A simplified algorithm for AI (Brain Activity Index) calculation is performed below.



EEG and EMG signals are registered from the electrodes applied on the frontotemporal area of the patient‘s head.

The registered signal is subjected to digital filtration: motion artifacts, power main disturbances and noise from electrosurgical equipment, other bioelectrical signals, etc. are removed.

The algorithm of EEG analysis includes statistical information on typical signs of various groups of anesthetics‘ impact on the patient‘s EEG. During the analysis, the level of compliance is established between the registered EEG signal and each type of consciousness depression.

As a result of data analysis, the following indicator values are obtained:

AI (Brain Activity Index);
SR – EEG Signal Suppression Rate, taking into account the total duration of segments with low-voltage activity (suppression segments) over the last minute. Displayed as a percentage. SR > 0 is usual at AI < 50.

Signal Quality

To get accurate data on anesthesia depth monitoring:

- assess the signal quality continuously;
- provide control of electrodes‘ impedance;
- prevent impedance values from increasing;
- minimize artifacts and other noise.

For this purpose, the following technical solutions are implemented in MGA module:

SQI (Signal Quality Index) is continuously monitored. It takes into account the values of EEG cable electrode‘ impedance, noise level from artifacts, high-frequency noise and power main disturbances within EEG, etc.

If SQI = 0, displaying the values of AI (Brain Activity Index), SR and EMG Component Level is blocked. A message on the most significant cause for SQI dropping is transferred.

The level of EEG signal noise is measured continuously.

Electrode impedance is an important parameter to indicate a quality of contact between skin and electrodes. Low impedance is an essential condition to get high quality signal.

MGA Module

Technical Specification

Patient age groups	Adults and children over 10 years old
Aneshetics	Works with both inhaled and intravenous anesthetics
Displayed parameters	Brain Activity Index EEG Signal Suppression Rate EEG Signal Quality Index Electromyographic component level Electrodes impedance (Z1–Z3)
The recommended types of electrodes	31.1245.21, 24 mm, Covidien LLC, USA; F9079/RU3236-100 FIAB SpA, Italy; White Sensor 40713 Ambu A/S, Denmark; G210C/F-150S Nihon Kohden Corporation, Japan.
Dimensions & Weght	115 x 65 x 25 mm, 0.2 kg
Power	Voltage: 5.0V ± 5% DC. Power consumption: 2W
Environment	0-40 °C, RH 40-80% (at air temperature +25 °C), 600-800 mm Hg
Intergation	UART interface, ODU connector
Standards	Developed in accordance with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-26, IEC 60601-2-40

OEM Delivery Kit

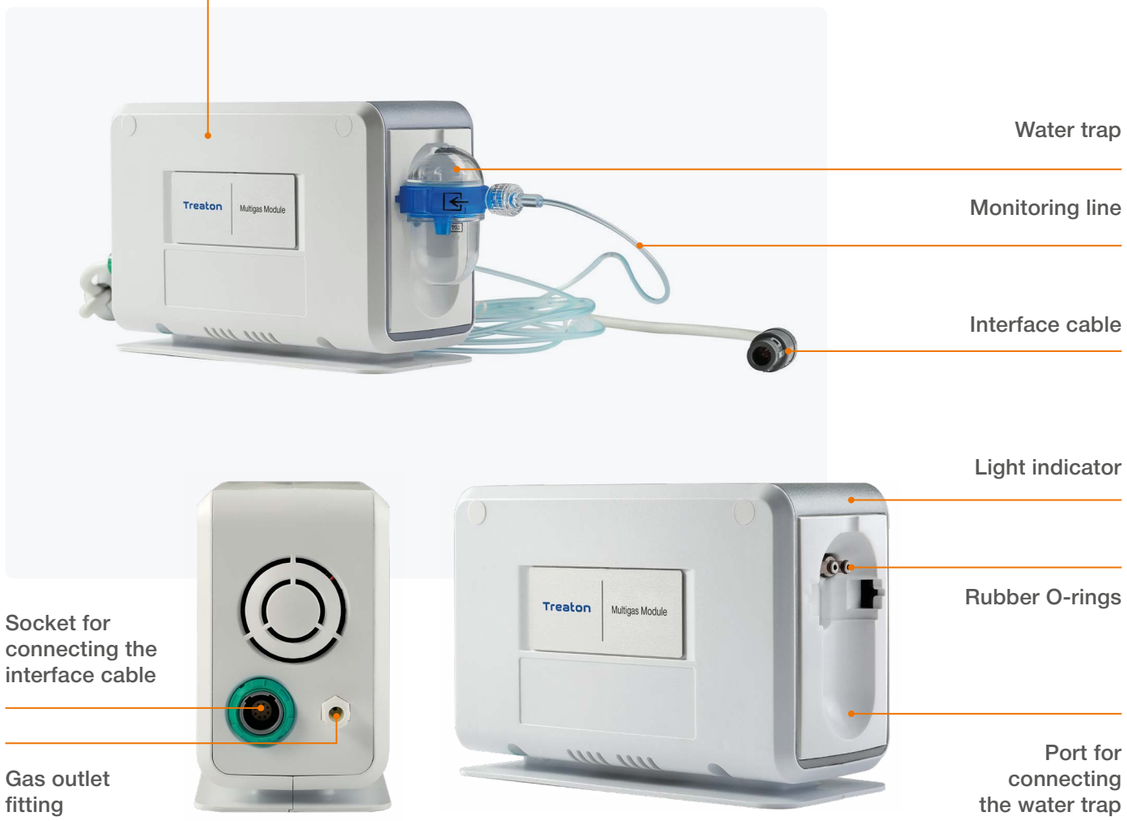
Depth of anesthesia and sedation module MGA	TESM.943129.007-02	1 pcs.
Electrodes	100 pcs.	

Multigas Module

Complete solution for anesthesiologists:
Anesthesia Gas Monitoring

Appearance

Multigas is anaesthesia gas analyzer intended for continuous sidestream measurement and monitoring of gas concentration in the patient's airways. Specially designed for implementation into medical devices, including anaesthesia machines, patient monitors and ventilators.



Multigas Benefits

- Easy integration.
- Maintenance-free.
- Standard accessories.
- No routine calibration.

Measured Parameters

Concentration of anesthetic gas agents (Ax):
Halotane (option), Isoflurane (Iso), Desflurane (Des),
Sevoflurane (Sev) on inspiration (FiAx) and expiration (EtAx).

Concentration of CO_2 on inspiration ($FiCO_2$)
and at the end of exhalation ($EtCO_2$).

Respiration rate (RR).

Concentration of O_2 (option) on inspiration (FiO_2)
and at the end of exhalation (EtO_2).

Agent Measuring Ranges

Gas	Measurement range, Vol %	Accuracy
Isoflurane (Iso)	0–5	±(0.2% + 15% of gas level)
Desflurane (Des)	0–17	±(0.2% + 15% of gas level)
Sevoflurane (Sev)	0–7	±(0.2% + 15% of gas level)
Halothane (Hal) (option)	0–5	±0.2
CO_2	0–15	± (0.43% + 8% of gas level)
O_2 (option)	0–100	±2

OEM Delivery Kit

Multigas Module	TESM.943129.001	1 pcs.
Water trap	60-1300-00 DRYLINE	1 pcs.
Sampling line	010-700 Flexicare	1 pcs.
Connector	15M-22M/15 REF2713 or 15M-22M/15 010-638 Flexicare	1 pcs.
Interface cable	TESM.704021-03	1 pcs.
Developer kit includes: RS232-USB converter; USB cable; CD with development software and data protocol description; Integration manual.	On request ET555494	1 pcs.

Technical Specification

Technology	Non-dispersive infrared (NDIR)
Measured gases	Anesthetic agents: Iso, Des, Sev, Hal (option), CO_2, O_2 (option)
Measured parameters	Inspired and expired gas concentrations of all gases; respiration rate; ambient pressure
Patient age groups	Adult, pediatric
Self-diagnosis	Availability
Warm-up time	ISO accuracy within 45 sec. Full accuracy within 10 min , CO_2 channel 10 sec.
Response time	2.5 sec
Resolution	0.1
Gas sampling rate	50–250 ml/min
Respiration rate range	0–160 breath per minute (BPM)
Respiration rate accuracy	± 1 breath
Apnea detection range	10–60 sec, default 20 sec
Calibration	No user calibration required. Supports automatic atmospheric pressure compensation
Dimensions & Weight	External module: 150x95x60 mm. 0.5 kg
Power	Voltage: 5 V ± 5% Power consumption: 2.5 W, not more than 5 W at the warm-up
Environment/Protection	Water and splash resistance: IP22 Operation: 10–35°C, RH 10–90% Storage: 5–40°C, RH <80% at 25°C, 390-900 mmHg Transportation: -50 to 50°C
Integration	Interface: RS232 Connector: 5-pin ODU Data output: $FiCO_2$, FiO_2, FiAx, $EtCO_2$, EtO_2, EtAx, Respiration rate
Standards	Developed in accordance with the requirements: EN 60601-1, IEC 60601-1-2, EN ISO 80601-2-55, MDD 93/42/EEC, RoHS

Mainstream CO_2 Sensor QuRe®

Mainstream CO_2 monitoring

CE

2460

QuRe® sensor is intended to measure $FiCO_2$ and $EtCO_2$ concentration in the mainstream breathing. Designed to use with medical devices for intensive care, ventilation, respiratory support and patient monitoring. The sensor is applicable for all intubated patients from adults to neonates.

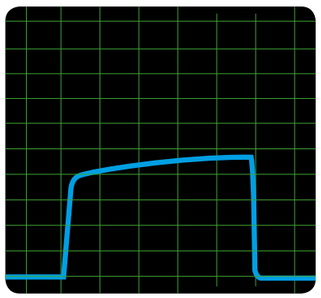
QuRe® Sensor Benefits

- The most acurate capnogram.
- Compact and lightweight.
- Long-life time reusable airway adapters, up to 100 sterilization cycles.
- Suitable for high-frequency ventilation, up to 200 BPM.
- No user calibration required.
- “Everything on board”: the measurement channel and analysis CPU are inside the sensor. This saves space in your own medical devices.
- Easy intergration to any monitoring or ventilation system, full technical support by the Manufacturer.
- Private labeling solutions (PLM) available.
- Fastest response time.

OEM Delivery Kit

	Part No.	Quantity
CO_2 Mainstream Sensor	TESM.506001	1
Reusable airway adapter		1
adult / pediatric	TESM.706020	
pediatric / neonate	TESM.706021	
Evaluation kit includes: RS232-USB converter, USB cable, CD with development sofware and data protocol description, integration manual	on request	1

The highest precision
of capnogram waveform
for true clinical diagnostics.



QuRe® data rate is 100 Hz and instant accurate response of the sensor to the changing CO_2 concentration.

The sensor contains an innovative ultrafast semiconductor emitter with a high modulation frequency of the signal.

Due to the precise capnography waveform, the clinicians can analyze each breathing cycle, detect respiratory disorders and provide optimal ventilation mode to a patient.

Technical Specifications

Sensor type	CO_2 mainstream sensor
Operation principle	Non-dispersive infrared (NDIR)
Initialization time	20 sec at an ambient t of 25°C. Full specification within 2 min
Response time	~10 ms
CO_2 measurement range	0–20% (0–150 mmHg)
CO_2 accuracy	0.2 Vol%
CO_2 resolution	0.1 Vol%
Respiration rate range	0–200 breath per minute (BPM)
Respiration rate accuracy	±1 breath
Apnea detection range	10–60 sec, default 20 sec
Calibration	No user calibration required
Airway adapters	Reusable adult / pediatric. Reusable pediatric / neonatal. Material: airway adapter — polycarbonate optical windows — sapphire glass. Dead space: <5 ml (adult / pediatric), <1 ml (pediatric / neonatal). Sterilization: ethylene oxide / autoclaving up to 100 times.
Dimensions & Weight	Sensor: 38x35x23 mm. Weight: 28 g. Cable length: 3 m
Power	Voltage: 5.0 V ± 5%. Power consumption: 1.3 W, not more then 3 W at the warm-up
Environment / Protection	Water and splash resistance: IP44 (sensor). Operation: 10 to 35°C, RH 10–90%, 390–900 mmHg. Storage: 5 to 40°C, RH <80% at 25°C. Transportation: –50 to 50°C
Integration	Interface: RS232. Connector: Lemo Redel / ODU Data output: $FiCO_2$, $EtCO_2$, Respiration rate. Gas and pressure compensation: available, supplied by host.

Sensor QuRe

Sidestream CO_2 Sensor

Easy integration

Intended use

Sidestream CO_2 sensor is intended for continuous noninvasive monitoring of fraction of inspired CO_2 ($FiCO_2$) and end tidal CO_2 ($EtCO_2$), respiration rate (RR) and apnea. Specially designed for implementation into medical devices for anesthesiology, intensive care, as well as patient monitors.

Scope Anesthesiology and intensive care departments of professional medical facilities, transportation within professional medical facilities

CO_2 monitoring is recommended by various international associations as a routine procedure for patients during anesthesia and in intensive care departments. *

Benefits

Easy integration

Maintenance-free

Standard accessories

No routine calibration

Clinical application

Assessing of the spontaneous breathing adequacy. Using the capnography the level of spontaneous breathing during recovery after anesthesia can be assessed;

Weaning from mechanical ventilation;

Controlling of breathing system hermetic seal. A gas leakage is always possible during anesthesia. The leakage can be detected by $EtCO_2$ monitoring, which value is gradually increasing due to hypoventilation;

Examination of circulatory arrest and resuscitation procedures effectiveness;

Capnometry is optimal method for monitoring of cardiopulmonary resuscitation (CPR) effectiveness;

Control during the trachea intubation;

Examination of ventilation-perfusion ratio mismatch;

Any cause that reduces the lungs perfusion and/or increases the respiratory dead space can lead to $PEtCO_2$ decreasing and $\Delta P(a\text{-}Et)CO_2$ increasing.

Monitoring of hypermetabolic conditions (malignant hyperthermia, thyroid crisis, sepsis, etc.).

References

1. ASA Standards for Basic Anesthetic Monitoring, Standards and Practice;

2. European Resuscitation Council Guidelines for Resuscitation;

3. American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care;

4. Association of Anaesthetists of Great Britain and Ireland. Recommendations for standards of monitoring during anaesthesia and recovery.

Appearance

OEM Delivery Kit

Sidestream CO_2 sensor	TESN.943129.008-01	1 pcs.
Connector	15M-22M/15 REF2713 or 15M-22M/15 010-638 Flexicare	*
Monitoring line	TESN.943129.008-01	1 pcs.
Water trap	60-1300-00 DRYLINE	1 pcs.
Interface cable	TESM.704021-03	1 pcs.

* The items and quantity of the accessories and documents are specified at the order.

Technical Specification

Parameter	Value (description)
Operation principle	Non-dispersive infrared spectrophotometry (NDIR)
Initialization time	10 s
Time of setting the operating mode	120 s (at ambient temperature 25°C)
Gas sampling rate accuracy	50-250 ml/min ±10 ml/min in absolute terms or ±10% in relative one (the biggest from the values)
CO_2 concentration measurement range	0–20 vol.% (resolution 0.1) 0–150 mmHg (resolution 0.1)
CO_2 measurement accuracy	±(0.2 vol.%+0.02·Kmeas) or ±(1.5 mmHg+0.02·Kmeas)
Measurements drift	±(0,2 vol.%+0.02·Kmeas) or ±(1.5 mmHg+0.02·Kmeas)
Response time	≈3 s
Rise time	0.2 s
Influence of gas impurities and vapors	±(0.43vol.%+0.08·Kmeas)
Respiratory rate measurement range Respiratory rate measurement accuracy	3–160 bpm ±2 bpm
Power	Voltage: 5.0 V ± 5 % Capacity 1.5 W, maximum 4 W during warming
Weight	0.5
Dimensions (without cable), width x height x depth	58x92x146 mm
Connector	Lemo Redel / ODU
Interface	RS-232

Operation conditions

Ambient temperature	10–35 °C
Relative humidity	10–90 % (at the temperature 25°C)
Ambient pressure	600 mmHg….800 mmHg

Transportation conditions

Ambient temperature	-50°C–50°C
Relative humidity	<80% (at the temperature 25°C)

Storage conditions

Ambient temperature	5–40°C
Relative humidity	<80% (at the temperature 25°C)

Standards

The device meets the safety requirements of EN 60601-1, EN ISO 80601-2-55.

The device is developed to meet the requirements of EN 60601-1-2 concerning electromagnetic compatibility (EMC).

Export Geography

Over 40 countries around the world

Great Britain	Indonesia	Syria
Germany	Malaysia	Egypt
Portugal	China	Turkey
Spain	Taiwan	Peru
Denmark	Sri Lanka	Uzbekistan
Ireland	Bangladesh	Kyrgyzstan
Hungary	Korea	Croatia
Czech Republic	Vietnam	Belarus
Poland	Philippines	
Slovakia	Thailand	
Moldova	Singapore	
India	South Africa	

We continuously improve the technological principles and implement new profitable solutions based on market demands

In biomedical signal processing, gas monitoring and respiratory support since 1989

12/5 Sibirskiy Trakt
Ekaterinburg, 620100
Russia

Quality management system certified as meeting the requirements of EN ISO 13485

First revision

September 2021